



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO.   |
|-----------------|-------------|--|---------------------|--------------------|
| 10/616,897      | 07/09/2003  | Holly A. Ingraham  | 66778-120           | 6612               |
| 41552           | 7590        | 07/05/2006   |                     | EXAMINER           |
|                 |             | MCDERMOTT, WILL & EMERY<br>4370 LA JOLLA VILLAGE DRIVE, SUITE 700<br>SAN DIEGO, CA 92122 |                     | BASI, NIRMAL SINGH |
|                 |             |  | ART UNIT            | PAPER NUMBER       |
|                 |             |  |                     | 1646               |

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/616,897             | INGRAHAM ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Nirmal S. Basi         | 1646                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 09 July 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-59 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-59 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-59, drawn to steroidal factor-I (SF-I)-like receptor variant or active fragment thereof, comprising an amino acid sequence encoding a SF-I-like receptor or an active fragment thereof, said amino acid sequence lacking at least one naturally occurring cysteine residue within the ligand-binding domain of said receptor, classified in class 530, subclass 350.

It has been determined that the Markush group claimed encompasses a plurality of independent and distinct inventions which require further restriction. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103.

The claims are drawn to a multitude of steroidal factor-I (SF-I)-like receptor variant molecules and apply to numerous structurally and functionally different polypeptides encompassing variants of human and murine SF-1, LRH-1, FTF, SF-1 $\beta$ .

Steroidogenic factor-1 (SF-1), an orphan receptor, is a monomeric nuclear receptor, which aggregates (page 1, specification). The variants claimed have different activities, stabilities and aggregation properties. The genus<sup>of</sup> claimed orphan receptor variants constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different SF-1-like receptor variants molecules are independent and distinct because they have variant structural and functional properties. There is no description of definitive structural or functional features of the claimed Markush group that predicts function based on structure.

The common function of the claimed genus of polypeptides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. Accordingly, these claims are subject to restriction under U.S.C 121. Applicants is required to elect a single SF-1-like variant lacking at least one naturally occurring cysteine residue within the ligand-binding domain. The elected single SF-1 like variant molecule lacking at least one naturally occurring cysteine residue within the ligand-binding domain of said receptor will therefore comprise the elected invention. **This requirement is not to be construed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.**

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

An election to prosecute one of the SF-1-like variant molecule lacking at least one naturally occurring cysteine residue within the ligand-binding domain of said receptor, listed above, must be made. Affirmation of this election must be made by applicant in responding to this Office action. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

**Advisory**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

254  
Nirmal S. Basi  
Art Unit 1646  
6/23/06

  
ROBERT S. LANDSMAN, PH.D  
PRIMARY EXAMINER